

Message

From: Rieth, Susan [Rieth.Susan@epa.gov]
Sent: 11/10/2015 11:57:46 PM
To: Newhouse, Kathleen [Newhouse.Kathleen@epa.gov]; Jones, Samantha [Jones.Samantha@epa.gov]
CC: Subramaniam, Ravi [Subramaniam.Ravi@epa.gov]; Galizia, Audrey [Galizia.Audrey@epa.gov]
Subject: RE: question: lit search updates post-SAB review

Agreed. We still need to circle back to the lit search section and figure out how to document the update. Ugh sums it up!
Sue

From: Newhouse, Kathleen
Sent: Tuesday, November 10, 2015 6:48 PM
To: Rieth, Susan <Rieth.Susan@epa.gov>; Jones, Samantha <Jones.Samantha@epa.gov>
Cc: Subramaniam, Ravi <Subramaniam.Ravi@epa.gov>; Galizia, Audrey <Galizia.Audrey@epa.gov>
Subject: RE: question: lit search updates post-SAB review

Thanks for weighing in Sue. Let's try to keep in touch regarding our literature search updates. I think I will use the remaining money on the BaP contract since it expires in a year. I will keep you in the loop as I work with the contractors on the literature search updates (after I get Samantha's blessing of course ;). I will have to think about how I want the results of these targeted searches tagged. Ugh.

-K

From: Rieth, Susan
Sent: Wednesday, October 28, 2015 5:01 AM
To: Newhouse, Kathleen <Newhouse.Kathleen@epa.gov>; Jones, Samantha <Jones.Samantha@epa.gov>
Cc: Subramaniam, Ravi <Subramaniam.Ravi@epa.gov>; Galizia, Audrey <Galizia.Audrey@epa.gov>
Subject: RE: question: lit search updates post-SAB review

Hi Kathleen,
Thanks for starting this discussion of post peer review lit searching. (I'm looping in Audrey since we had a similar discussion yesterday). And also some responses to specific questions (in red) below.

The ammonia SAB recommendations regarding an updated lit search were more general, perhaps, than BaP:

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP) Audrey is reviewing the lit search update now. And I'm just hoping we don't find any studies that would substantively change our conclusions!

Sue

From: Newhouse, Kathleen
Sent: Tuesday, October 27, 2015 7:07 PM

To: Jones, Samantha <Jones.Samantha@epa.gov>; Rieth, Susan <Rieth.Susan@epa.gov>

Cc: Subramaniam, Ravi <Subramaniam.Ravi@epa.gov>

Subject: RE: question: lit search updates post-SAB review

Hi all, after chatting with Samantha and Sue about this a bit, I thought I would put some of my issues in writing so I don't forget after I return from leave (I also have hope that you guys can solve all my tough issues while I am away! ☺).

Is it now general practice to do a full update (systematic, documented literature search) post external peer review but to invoke the stopping rules and only include additional studies if they are expected that they will substantially change the conclusions of the assessment (and in that case I would expect additional peer review might be triggered)? I'd like to talk more about this. What about adding selected studies that support the conclusions you already reached? (i.e., what the ammonia panel asked for.)

Also, in this new world of systematic, documented literature searches, are there any good examples of targeted literature searches done in response to external peer review comments? None that I know of. We haven't gotten there yet with ammonia. But we should try to work together on this. I want to make sure I can get this done in a documented and systematic way. I have a contract for SRC support for response to SAB comments (I have about 100K left on it-I'll have to check on the period of performance on my contract). I expect the POP for the BaP TO ends in August 2016 with the rest of the BPA. I think all the old TOs set up by Brenda had a POP the same as the BPA itself (which didn't fly once we lost Brenda!) I could probably do this lit search update under this mechanism or under the general literature search task order.

Ex. 5 Deliberative Process (DP)

General question, do we suggest search terms/keywords for these targeted searches or is this something the contractor handles? I would probably get help from the contractor with these targeted searches.

Ok, sorry for the brain dump! Talk to you guys in November!

-Kathleen

From: Jones, Samantha

Sent: Thursday, April 09, 2015 7:56 PM

To: Rieth, Susan <Rieth.Susan@epa.gov>; Cogliano, Vincent <cogliano.vincent@epa.gov>; Perovich, Gina <Perovich.Gina@epa.gov>; DeSantis, Joe <DeSantis.Joe@epa.gov>; Cooper, Glinda <Cooper.Glinda@epa.gov>; Hogan, Karen <Hogan.Karen@epa.gov>; Hotchkiss, Andrew <Hotchkiss.Andrew@epa.gov>; Persad, Amanda <Persad.Amanda@epa.gov>; Newhouse, Kathleen <Newhouse.Kathleen@epa.gov>

Cc: Galizia, Audrey <Galizia.Audrey@epa.gov>

Subject: RE: question: lit search updates post-SAB review

You should do an updated literature search after you receive the final peer review report so that you might take their recommendations into account. Also, please see the Stopping Rules which basically supports the assertion that we generally add only studies that can impact the assessment conclusions after peer review. However, with current systematic review approaches, we need to make sure that this updated literature search is well-documented.

From: Rieth, Susan

Sent: Thursday, April 09, 2015 3:59 PM

To: Cogliano, Vincent; Jones, Samantha; Perovich, Gina; DeSantis, Joe; Cooper, Glinda; Hogan, Karen; Hotchkiss, Andrew; Persad, Amanda; Newhouse, Kathleen

Cc: Galizia, Audrey

Subject: question: lit search updates post-SAB review

Hi all,

I wanted to float a lit search update question by you...

As Audrey and I observed, the ammonia assessment lit search was updated several months before the assessment was released for SAB review (Aug 2013). The lit search is now about 2 years out of date, and I expect by the time the assessment is posted, it will be 3 years out of date. I expect this will be a pretty typical situation.

Has consideration been given to whether there are situations in which a lit search update should be performed after peer review? If posting happened closer to the time of the peer review draft, I wouldn't consider this a problem. But posting an assessment with a lit search so out of date looks lame. That said, I recognize that it's problematic to add significant new literature after the assessment has gone to peer review (except perhaps where the peer reviewers asked for additional support), lest we trigger another round of peer review!

The draft Handbook provides the following guidance:

"A cut-off date is used for various steps (e.g., the literature search released in Public Release I covers a specified time period). An additional cut-off date is used for subsequent steps, such as finalization of the external peer review draft. Notably, after a certain step of the process (e.g., external peer review), additional studies will only be added if it is expected that they will substantially change the conclusions of the assessment; thus, a full literature search update covering all topics will no longer be necessary."

There was a several year period when we did do post-peer review lit search updates and added the following text to the Tox Review introduction (example from biphenyl):

"A comprehensive literature search was last conducted in September 2012. No major epidemiology studies or subchronic and chronic animal studies on biphenyl were identified since the draft Toxicological Review (dated September 2011) was released for external peer review and public comment."

I expect an Assessment Manager would do their own informal lit searches during and after peer review just so they know if there's significant new literature, but this informal lit searching wouldn't be reflected in the Tox Review.

Just wanted to float this concern about out-of-date lit searches in our posted Tox Reviews. Let me know if you have any thoughts...

Thanks,

Sue